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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,385	01/03/2001	Michael W. Heartlein	10278-025004	2793

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/753,385

Applicant(s)

HEARTLEIN ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43-86 is/are pending in the application.
- 4a) Of the above claim(s) 44,47-50,52-63,65-67,70,72-76,80,81 and 83-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43,64,69,77-79 and 82 is/are rejected.
- 7) ☒ Claim(s) 43,45,46,51,54,68,69,71,77 and 86 is/are objected to.
- 8) ☒ Claim(s) 43-86 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

The amendment filed 11/26/03 has been entered.

#### ***Election/Restrictions***

Applicant's election of the species of endogenously produced substance being glycosaminoglycan and cell surface receptor being transferrin receptor in the paper filed November 26, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claim 52-63, 65-67, 70, 72-76 and 80-85 are completely directed to non-elected species, and are withdrawn from consideration at present for the reasons set forth in the previous Office action on page 2.

The first species elected, endogenously produced substance GAG and cell surface receptor transferrin receptor, is free of the prior art.

Claim 43, 45, 46, 51, 64, 68, 69, 71, 77-79, 82 and 86 are now under consideration as pertaining to the species under examination: endogenous substance GAG with cell surface receptor the transferrin receptor, and endogenous substance cytokine with cell surface receptor the Fc immunoglobulin receptor.

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#### ***Response to Amendment***

The rejection of claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims.

The rejection of claims 43 and 51 under 35 USC 102(b) as anticipated by Capon et al. is withdrawn in view of the amendment to the claims.

The rejection of claims 43 and 51 under 35 USC 102(a) as anticipated by Shin et al. is withdrawn upon further reconsideration since the chimeric protein of Shin comprises two carrier domains (IgG3 which binds FcR and transferrin which binds TfR) and no functional domain.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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### ***Claim Objections***

Claims 43, 45, 54, 69 and 77 are or remain objected to for reciting or encompassing non-elected species.

Claims 46 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and including the limitations of both claims 46 and 51. With such an amendment limiting the claim to the species of 46 and 51, dependent claim 68 would also be allowable.

The immediately above objection is the same for claims 71 and 86.

Claim 79 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 79 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 79 recites the limitation "the GAG" in line 5. There is insufficient antecedent basis for this limitation in the claim. The glycosaminoglycans are a defined *family* of molecules, and no one particular GAG was specified in the claim prior to line 5. Therefore, there is no antecedent basis for "the GAG" (see also line 8, which suffers the same problem). This rejection could be overcome by replacing "the GAG" with --a GAG--.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 43, 64, 69, 77, 78 and 82 are rejected under 35 U.S.C. 102(e) as being anticipated by Beutler et al. (AI, US Patent 5,447,851, cited by Applicant) as evidenced by Romet-Lemonne et al. (US Patent 6,258,358) or Capon et al. (AV, Nature, 337(9):525, 1989, cited by Applicant). Note that the Romet-Lemonne et al. and Capon et al. references are evidentiary only, and that all claim limitations are met by the single Beutler reference.

Beutler et al. teach a chimeric polypeptide composed of the ligand binding domain of TNF cytokine receptor (TNFR, a functional domain) fused to portions of IgG (a carrier domain), including the Fc portion of IgG (Fig. 1B and col. 7, lines 25-34). Also, after administration of the chimeric protein to a mouse subject, it crossed the placenta and was detected in blood (col. 23, lines 27-42). Beutler et al. is silent with respect to lowering amounts of endogenous. However, the artisan of ordinary skill would have reasonably expected that the TNFR-IgG chimeric protein would have been internalized and, necessarily, would have lowered the amount of endogenous TNF in light of the statement of Romet-Lemonn et al. or showing of Capon et al. that IgG binds Fc receptors and is internalized (see below).

Romet-Lemonne et al. (col. 9, lines 6-9) say that, "The preferred surface receptors of antigen-presenting cells for targeting are the receptors for the Fc region of IgG (FcγR). These receptors mediate internalization of antibody-complexed antigens." Capon et al. teach a CD4-IgG chimeric protein (legend of Fig. 1, end of first paragraph) which binds an Fc receptor. It was shown that the IgG portion of the chimeric protein bound Fc receptor, and increased half-life of the chimeric protein and its transport into a cell (e.g., p. 527 and p. 530, col. 2, first full paragraph). Note that neither Romet-Lemonne et al. nor Capon et al. is required for anticipation, but is relied upon solely to show the inherent property of receptor-mediated internalization of the IgG portion of the chimeric protein of Beutler et al.

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*Conclusion*

Claim 79 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571)272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571)272-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

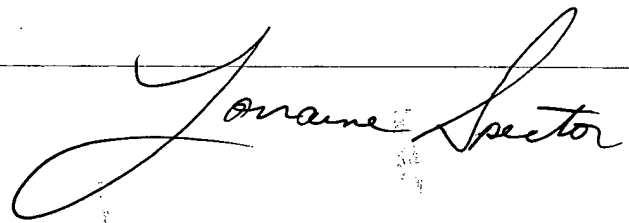
Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.


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Patent Examiner, Art Unit 1646

February 5, 2004



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